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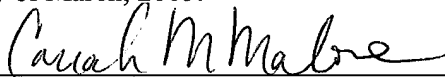
PATENT
Attorney Docket No. MEE-002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Miller *et al.*
SERIAL NO.: 09/780,142 GROUP NO.: 1644
FILING DATE: February 9, 2001 EXAMINER: Huynh, P.
TITLE: METHODS AND COMPOSITIONS FOR TREATING CONDITIONS
OF THE EYE

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 24th day of March, 2005.


Carrah M. Malone

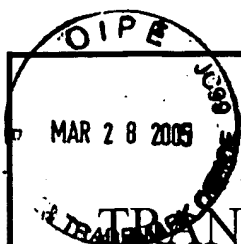
Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith is/are:

1. Transmittal Form (1 page);
2. Fee Transmittal (1 page);
3. Check in the amount of \$180.00;
4. Supplemental Information Disclosure Statement (2 pages),
5. Form PTO 1449 (4 pages);
6. Copies of cited references B8-B11 and C119-C169; and
7. Return Receipt Postcard

VER 9/00



TRANSMITTAL FORM

Application Serial Number	09/780,142
Filing Date	February 9, 2001
First Named Inventor	Miller
Group Art Unit	1644
Examiner Name	Huynh, P.
Attorney Docket No.	MEE-002
Patent No.	Not applicable
Issue Date	Not applicable

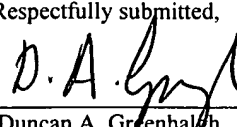
ENCLOSURES (check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form <input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets _____] <input type="checkbox"/> Petition for Extension of Time <input checked="" type="checkbox"/> Supplemental Information Disclosure Statement (2 pgs.) <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations (B8-B11 and C119-C169) <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application <input type="checkbox"/> Formal Drawing(s) <input type="checkbox"/> Request For Continued Examination (RCE) Transmittal <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers) <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application <input type="checkbox"/> Small Entity Statement <input type="checkbox"/> CD(s) for large table or computer program <input type="checkbox"/> Amendment After Allowance <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences <input type="checkbox"/> Appeal Brief (in triplicate) <input type="checkbox"/> Status Inquiry <input checked="" type="checkbox"/> Return Receipt Postcard <input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8 <input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8 <input type="checkbox"/> Additional Enclosure(s) (please identify below)
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SIGNATURE BLOCK

Respectfully submitted,

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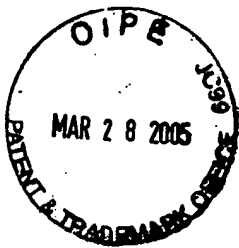
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Attorney Docket No.	MEE-002
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TOTAL	(\$)	180.00
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Attorney Docket No. MEE-002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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SERIAL NO.: 09/780,142 GROUP NO.: 1644
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TITLE: METHODS AND COMPOSITIONS FOR TREATING CONDITIONS
OF THE EYE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. In accordance with 37 C.F.R. 1.98(a)(2), only copies of the foreign patent documents and non-patent publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

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- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

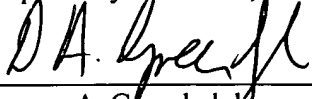
- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Date: March 24, 2005
Reg. No. 38,678

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VER 11/03

Respectfully submitted,



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FORM PTO - 1449 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT				ATTORNEY DOCKET NO.: MEE-002 APPLICANTS: Miller <i>et al.</i> SERIAL NO.: 09/780,142 FILING DATE: February 9, 2001 EXAMINER: Huynh, P. GROUP: 1644					
U.S. PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	A9	2002/0049247	4/25/2002	Chen					
	A10	2003/0171320	9/11/2003	Guyer <i>et al.</i>					
	A11	2004/0167091	8/26/2004	Guyer <i>et al.</i>					
	A12	2005/0043220	2/24/2005	Guyer <i>et al.</i>					
	A13	6,270,749	8/7/2001	Blumenkranz <i>et al.</i>					
FOREIGN PATENT DOCUMENTS									
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B8	WO 97/05127	2/13/1997						
	B9	WO 00/40089	7/13/2000						
	B10	WO 01/58240	8/16/2001						
	B11	WO 03/039404	5/15/2003						
OTHER ART, JOURNAL ARTICLES, ETC.									
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)								
	C119	"A Clinical Trial to Evaluate the Effect of an Experimental Compound on Reducing the Number of Retreatments Required in Photodynamic Therapy (PDT) with Visudyne™," Alcon web site, http://www.alconlabs.com/us/co/c-00-07study.ihtml (printed April 4, 2003).							
	C120	Adamis, "Looking Forward: Ocular Biochemical Warfare - The VEGF Attack," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).							
	C121	Behling <i>et al.</i> , "Adeno-associated Delivery of TIMP-3 Inhibits Experimental Choroidal Neovascularization," <i>Invest. Ophthalmol Vis Sci</i> , 44: E-Abstract 1425 (2003).							
	C122	Blumenkranz <i>et al.</i> , "Verteporfin therapy for subfoveal choroidal neovascularization in age-related macular degeneration: three-year results of an open-label extension of 2 randomized clinical trials--TAP Report no. 5," <i>Arch Ophthalmol</i> , 120(10):1307-14 (Oct. 2002).							
	C123	Bressler, "Photodynamic Therapy for AMD: Re-treatment Considerations," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).							
	C124	Campochiaro <i>et al.</i> , "The pathogenesis of choroidal neovascularization in patients with age-related macular degeneration," <i>Molecular Vision</i> 5: 34-8 (Nov. 3, 1999).							
	C125	Ciulla <i>et al.</i> , "Age-Related Macular Degeneration: A Review of Experimental Treatments," <i>Surv. Ophthalmol</i> , 43(2): 134-46 (1998).							
	C126	Corjay <i>et al.</i> , "alpha _v beta ₃ , alpha _v Beta ₃ , and Osteopontin Immunostaining in Experimental Choroidal Neovascularization in the Monkey," Presentation #4473, Abstract on pg. S965.							
EXAMINER					DATE CONSIDERED				

FORM PTO - 1449

SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT

ATTORNEY DOCKET NO.: MEE-002

APPLICANTS: Miller *et al.*

SERIAL NO.: 09/780,142

FILING DATE: February 9, 2001

EXAMINER: Huynh, P. GROUP: 1644

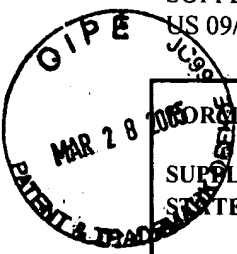
OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C127	Csaky, K., "Anti-vascular endothelial growth factor therapy for neovascular age-related macular degeneration: promises and pitfalls (Comment)," <u>Ophthalmology</u> 110(5):879-81 (May 2003).
	C128	Dahlin <i>et al.</i> , "Design of a Specialized Cannula for Poserior Juxtapapillary Delivery of Anecortave Acetate to the Retina for Treatment CNV Associated with Age-Related Macular Degeneration," Invest. Ophthalmol Vis Sci. 44: E-Abstract 5036 (2003).
	C129	Danis, "Pharmacotherapy for AMD: The Role of Intravitreal Steroids and Related Agents," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).
	C130	de Juan, "Surgery for AMD: Limited Translocation in the Era of Photodynamic Therapy," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).
	C131	Eyetechnology Study Group, "Anti-vascular endothelial growth factor therapy for subfoveal choroidal neovascularization secondary to age-related macular degeneration: phase II study results," <u>Ophthalmology</u> 110(5):979-86 (May 2003).
	C132	Gallemler <i>et al.</i> , "AMD Treatment Update: Along with Visudyne and TTT, injectable anti-angiogenesis agents are on the forefront of current research," <u>Ophthalmology Management</u> , 69-72 (March 2003).
	C133	Gauthier <i>et al.</i> , "Safety and Efficacy of Intravitreal Injection of rhuFab V2, an Anti-vascular Endothelial Growth Factor (VEGF) in Combination With Verteporfin PDT on Experimental Choroidal Neovascularization," <u>ARVO Poster</u> .
	C134	Gauthier <i>et al.</i> , "Safety and Efficacy of Intravitreal Injection of rhuFab VEGF in Combination With Verteporfin PDT on Experimental Choroidal Neovascularization," <u>ARVO, The Association for Research in Vision and Ophthalmology</u> (Oasis, Online Abstract Submission and Invention System, Program Planner, Presentation # 566).
	C135	Granville <i>et al.</i> , "Fas ligand and TRAIL augment the effect of photodynamic therapy on the induction of apoptosis in JURKAT cells," <u>International Immunopharmacology</u> 1: 1831-40 (2001).
	C136	Guyer, D.R., "Pharmacotherapy for AMD: VEGF Inhibitors and Related Agents," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).
	C137	Haimovici <i>et al.</i> , "Localization of Lipoprotein-delivered benzoporphyrin derivative in the rabbit eye," <u>Curr. Eye Res.</u> 16(2):83-90 (1997).
	C138	Heier <i>et al.</i> , "rhuFAB V2 (an Anti-VEGF Antibody Fragment) in Neovascular AMD: Safety and Tolerability of Multiple Intravitreal Injections - Preliminary Data from a Single Center," <u>ARVO Poster</u> .
	C139	Husain <i>et al.</i> , "Effects of Photodynamic Therapy Using Verteporfin on Experimental Choroidal Neovascularization and Normal Retina and Choroid up to 7 Weeks after Treatment," <u>Invest. Ophthalmol Vis Sci.</u> 40(10): 2322-31 (1999).
	C140	Husain <i>et al.</i> , "Photodynamic therapy and digital angiography of experimental iris neovascularization using liposomal benzoporphyrin derivative," <u>Ophthalmology</u> 104(8):1242-50 (Aug. 1997).
	C141	International Search Report for PCT/US01/04231 completed on November 23, 2001
	C142	Kaiser <i>et al.</i> , "Five-Year Results of Verteporfin Therapy for Subfoveal CNV Due to AMD: Third Year of an Open-label Extension of the TAP Investigation," <u>Invest. Ophthalmol Vis Sci.</u> 44: E-Abstract 1099 (2003).
	C143	Kitchen <i>et al.</i> , "Anecortave Acetate Monotherapy for the Treatment of Occult and Minimally Classic Choroidal Neovascularization in Age-related Macular Degeneration," <u>Invest. Ophthalmol Vis Sci.</u> 44: E-Abstract 5039 (2003).
EXAMINER		DATE CONSIDERED

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

US 09/780,142

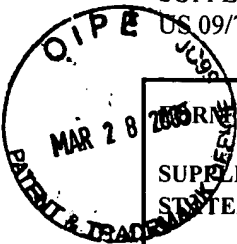
Sheet 3 of 4

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OTHER ART, JOURNAL ARTICLES, ETC.		
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C144	Kliman <i>et al.</i> , "Angiography and Photodynamic Therapy of Experimental Choroidal Neovascularization using Phthalocyanine Dye," <i>Invest. Ophthalmol. Vis. Sci. (Suppl.)</i> 30(3): 371 (1989).
	C145	Krzystolik <i>et al.</i> , "Prevention of Experimental Choroidal Neovascularization With Intravitreal Anti-Vascular Endothelial Growth Factor Antibody Fragment," <i>Arch. Ophthalmol.</i> 120(2): 338-346 (2002).
	C146	Lai <i>et al.</i> , "Suppression of Choroidal Neovascularization by Adeno-associated Virus Vector Expressing Angiostatin," <i>Investigative Ophthalmology & Visual Science</i> 42 (10): 2401-2407 (2001).
	C147	Leibowitz <i>et al.</i> , "The Framingham Eye Study Monograph: An ophthalmological and epidemiological study of cataract, glaucoma, diabetic retinopathy, macular degeneration, and visual acuity in a general population of 2631 adults," <i>Survey of Ophthalmology, Supplement</i> (May-June 1980).
	C148	Miller, "Photodynamic Therapy for AMD: Expanded Indications," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).
	C149	Ngo <i>et al.</i> , "Computational Complexity, Protein Structure Prediction, and Levinthal Paradox," Chapter 14 of <i>The Protein Folding and Tertiary Structure Prediction</i> , Merz and LeGrand, Eds., Burkhauser Boston, 1994.
	C150	Oleinick <i>et al.</i> , "The role of apoptosis in response to photodynamic therapy: what, where, why, and how," <i>Photochem. Photobiol. Sci.</i> 1: 1-21 (2002).
	C151	Olsen <i>et al.</i> , "An Evaluation of an Episcleral Ancortave Acetate Transscleral Drug Delivery System in Rhesus Monkey," <i>Invest. Ophthalmol Vis Sci.</i> 44: E-Abstract 4213 (2003).
	C152	Pasqualini <i>et al.</i> , "Organ Targeting in Vivo using Phage display Peptide Libraries," <i>Nature</i> 380: 364-6 (1996).
	C153	Reinke <i>et al.</i> , "Verteporfin photodynamic therapy retreatment of normal retina and choroid in the cynomolgus monkey," <i>Ophthalmology</i> 106(10):1915-23 (Oct. 1999).
	C154	Renno <i>et al.</i> , "Expression of pigment epithelium-derived factor in experimental choroidal neovascularization," <i>Invest Ophthalmol Vis Sci.</i> 43(5):1574-80 (May 2002).
	C155	Renno <i>et al.</i> , "Photodynamic therapy using Lu-Tex induces apoptosis in vitro, and its effect is potentiated by angiostatin in retinal capillary endothelial cells," <i>Invest Ophthalmol Vis Sci.</i> 41(12):3963-71 (Nov 2000).
	C156	Renno <i>et al.</i> , "Photosensitizer delivery for photodynamic therapy of choroidal neovascularization." <i>Adv Drug Deliv Rev.</i> 52(1):63-78 (Oct. 31, 2001) Review.
	C157	Renno <i>et al.</i> , "Selective photodynamic therapy by targeted verteporfin delivery to experimental choroidal neovascularization mediated by a homing peptide to vascular endothelial growth factor receptor-2," <i>Arch Ophthalmol.</i> 122(7):1002-11 (July 2004).
	C158	Schlingemann <i>et al.</i> , "Role of vascular permeability factor/vascular endothelial growth factor in eye disease," <i>Br. J. Ophthalmol.</i> 81: 501-12 (1997)
	C159	Schmidt-Erfurth <i>et al.</i> , "Photodynamic therapy with verteporfin for choroidal neovascularization caused by age-related macular degeneration: results of retreatments in a phase 1 and 2 study," <i>Arch Ophthalmol.</i> 117(9):1177-87 (Sept. 1999). Erratum in: <i>Arch Ophthalmol.</i> 118(4):488 (April 2000).
	C160	Sickenberg <i>et al.</i> , "A preliminary study of photodynamic therapy using verteporfin for choroidal neovascularization in pathologic myopia, ocular histoplasmosis syndrome, angioid streaks, and idiopathic causes." <i>Arch Ophthalmol.</i> 118(3):327-36 (March 2000).
	C161	Slakter <i>et al.</i> , "Ancortave Acetate Administered as a Posterior Juxtascleral Injection for Subfoveal CNV in Age-Related Macular Degeneration (AMD-Clinical Results)," Presentation at the Retina Congress 2002 Symposium (Sept. 8, 2002).
EXAMINER		DATE CONSIDERED

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

US 09/780,142

Sheet 4 of 4

 RECEIPT - 1449 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO.: MEE-002 APPLICANTS: Miller <i>et al.</i> SERIAL NO.: 09/780,142 FILING DATE: February 9, 2001 EXAMINER: Huynh, P. GROUP: 1644
OTHER ART, JOURNAL ARTICLES, ETC.		
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C162	Slakter, "Pharmacotherapy for AMD: The Role of Periocular Steroids and Related Agents," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).
	C163	Slakter <i>et al.</i> , "Sub-Tenon's Administration of the Angiostatic Agent Anecortave Acetate in AMD Patients with Subfoveal Choroidal Neovascularization (CNV) - the Clinical Outcome," <i>Invest. Ophthalmol Vis Sci.</i> 44: E-Abstract 2909 (2002).
	C164	Slakter <i>et al.</i> , "Verteporfin With Altered (Delayed) Light in Occult CNV (VALIO) - Results of a Phase II Controlled Clinical Trial," <i>Invest. Ophthalmol Vis Sci.</i> 44: E-Abstract 1101 (2003).
	C165	Trese, "Treatment of Neovascularization in ROP: Pharmacological Agents and the ERTOP Study," American Academy of Ophthalmology Meeting (Retina, Giant Steps: A Look at the Past - An Eye on the Future) Subspecialty Day (The Wet Story: Exudative Age-Related Macular Degeneration) Presentation, Orlando, Fla. (Oct. 18-19, 2002).
	C166	Verma <i>et al.</i> , "Gene therapy - Promises, problems and prospects," <i>Nature</i> 389: 239-42 (Sept. 1997).
	C167	Yaacobi <i>et al.</i> , "In-Vivo Studies with Trans-Scleral Anecortave Acetate Delivery Device Designed to Treat Choroidal Neovascularization in AMD," <i>Invest. Ophthalmol Vis Sci.</i> 44: E-Abstract 4210 (2003).
	C168	Zacks <i>et al.</i> , "Caspase Activation in an Experimental Model of Retinal Detachment," <i>Investigative Ophthalmology & Visual Science</i> 44(3): 1262-7 (March 2002).
	C169	Zacks <i>et al.</i> , "Verteporfin Photodynamic Therapy in the Rat Model of Choroidal Neovascularization: Angiographic and Histologic Characterization," <i>Investigative Ophthalmology & Visual Science</i> 43 (0): 1-9 (2002).
EXAMINER		DATE CONSIDERED